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- (b) high affinity to cation-exchange resins and heparin derivatives;
  - (c) inhibitory activity for osteoclast differentiation and/or maturation, wherein said activity is decreased by heating said protein at about 70°C for about 10 min. or at about 56°C for about 30 min., and wherein said activity is lost by heating at about 90°C for about 10 min.; and
  - (d) an internal amino acid sequence as provided in SEQ. ID NOS. 1, 2 or 3;

wherein said monoclonal antibody is produced by a hybridoma selected from the group consisting of AIG5 having Accession No. FERM BP-7441, D2F4 having Accession No. FERM BP-7442, and E3H8 having Accession No. FERM BP-7443 binding sites.

### REMARKS

#### Status of the Claims

Claims 36-49 are pending in this application with claim 36 being withdrawn by the Examiner as being drawn to a non-elected invention. Claim 49 is amended and claim 36 is canceled herein.

The Examiner has objected to the repeated use of certain trademarks throughout the specification. Applicants will submit a revised substitute specification appropriately amending the use of the trademarks upon identification of allowable subject matter.

#### Claim Rejections under 35 U.S.C. §112, First Paragraph

Claims 37-40 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains or with which it is most nearly connected, to make and/or use the invention. The Examiner requires an affidavit or declaration that the hybridomas, FERM BP-7441, FERM BP-7442, and FERM BP-7443, must be known and readily available to the public. Applicants respectfully submit that a deposit was made under the provisions of the Budapest Treaty. Deposit Receipt for each of FERM BP-7441, FERM BP-7442 and FERM BP-7443 and an affidavit signed by one in a position to corroborate the biological deposit meeting the requirements under 37 C.F.R.

§1.801-1.809 was submitted with the Preliminary Amendment mailed to the U.S. Patent Office on May 2, 2001. A copy of the Deposit Receipts and the affidavit corroborating deposit are attached herewith as Exhibit A.

In the Preliminary Amendment mailed to the Patent Office on May 2, 2001, Applicants requested that the specification be amended on page 86, after line 4 and before "Industrial availability," to include the following paragraphs:

--Samples of the hybridomas that produce the claimed monoclonal antibodies were deposited in the National Institute of Bioscience and Human Technology National Institute of Advanced Industrial Science and Technology. The National Institute of Bioscience and Human Technology National Institute of Advanced Industrial Science and Technology accession numbers for the deposited hybridomas are:

Hybridoma Antibody Designation	Deposit Date	Accession No.
A1G5	2/5/01	FERM BP-7441
D2F4	2/5/01	FERM BP-7442
E3H8	2/5/01	FERM BP-7443

These deposits were made under the Budapest Treaty and will be maintained and made accessible to others in accordance with the provisions thereof.--

Applicants submit herewith a Statement on the Availability of Deposited Material from one in a position to know that all restrictions imposed by the depositor on the availability to the public of the hybridomas, A1G5, D2F4, and E38H which were deposited on February 5, 2001 as Accession Nos. FERM BP-7441, FERM BP-7442, and FERM BP-7443, respectively, in the National Institute of Bioscience and Human-Technology National Institute of Advanced Industrial Science and Technology, will be irrevocably removed upon granting of a patent on the instant application.

Thus, Applicants have satisfied the requirement that all restrictions on the availability to the public of the deposited material is irrevocably revoked.

Claim Rejections under 35 U.S.C. §112, Second Paragraph

Claim 49 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants' amendments to claim 49 should satisfy the Examiner's rejections in this regard.

Applicants respectfully request that claims 37-49 be reconsidered and the rejections withdrawn.

CONCLUSION

Applicants respectfully submit that claims 37-49 are now in condition for allowance. If the Examiner believes that a telephone conversation would expedite prosecution of this application, he or she is invited to call the undersigned at (617) 248-7044.

Respectfully submitted,

Date: December 10, 2001  
Reg. No. 44,244  
Tel. No.: (617) 248-7044  
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**MARKED-UP COPY OF THE AMENDED CLAIMS**

49. A monoclonal antibody comprising a binding site which binds to osteoclastogenesis inhibitory factor protein, [comprising] said protein characterized by:

- (a) molecular weights as determined by SDS-polyacrylamide gel electrophoresis (SDS-PAGE) of approximately 60 kD under reducing conditions, and  
  
approximately 60 kD (a monomer) and 120 kD (a homodimer) under non-reducing conditions;
- (b) high affinity to cation-exchange resins and heparin derivatives;
- (c) inhibitory activity for osteoclast differentiation and/or maturation, wherein said activity is decreased by heating said protein at about 70°C for about 10 min. or at about 56°C for about 30 min., and wherein said activity is lost by heating at about 90°C for about 10 min.; and
- (d) an internal amino acid sequence as provided in SEQ. ID NOS. 1, 2 or 3;

wherein said monoclonal antibody [comprises a binding site] is produced by a hybridoma selected from the group consisting of [A1GF] AIG5 having Accession No. FERM BP-7441, D2F4 having Accession No. FERM BP-7442, and E3H8 having Accession No. FERM BP-7443 binding sites.